UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,902	05/31/2001	Jonathan Robert Lamb		7755

20999 7590 02/11/2003

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
DECLOUX, AMY M	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,902	LAMB ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

.tinuation of Attachment(s) 6). Other: Notice to COmoply with Requirements for Sequence Disclosures.

DETAILED ACTION

Applicant's Amendment and election filed 12-2-02 (Paper No. 8) is acknowledged and has been entered.

The examiner is not clear what Applicant means by stating in the Remarks Section (lines 2-3 of page 6), that reconsideration and withdrawal of the rejections of this application are requested since no rejections have been applied. Nor is it clear what Applicant means by the statement in lines 9-10 of said page that the claims are patentably distinct from the references cited by the Examiner, since the Examiner has not cited any references.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Sequences are disclosed in the specification which are not identified by a SEQ ID NO: tag. Specifically, 16 sequences without SEQ ID NO: tags are disclosed on pages 23 and 24. Applicants are required to resubmit a substitute disk and paper copy of the sequences according to the attached "Notice to Comply with the Sequence Rules." Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Claims 1-18 and newly added claims 19-34 are pending. In view of the newly added claims and Applicant's remarks, and upon reconsideration of the restriction requirement mailed 10-1-02 (Paper No. 7), said restriction requirement has been modified as follows.

Election/Restrictions

I. Claims 1-11 and newly added claims 19-21, 25-26, 28-30 and 33-34, drawn to a method for producing a lymphocyte or APC having tolerance to an allergen or an antigen, comprising incubating a lymphocyte or APC with a composition capable of upregulating expression of an endogenous Notch or Notch ligand and the allergen or antigen, classified in class 435, subclass 325.

II. Claims 13-16, drawn to use of a composition capable of upregulating expression of an endogenous Notch or Notch ligand in an APC or lymphocyte in a method of producing regulatory lymphocytes capable of suppressing the activity of other lymphocytes, classified in class 435, subclass 7.24.

III. Claims 12, 17 and 32, drawn to a method of treating a patient suffering from a disease characterized by inappropriate lymphocyte activity comprising

administering a lymphocyte produced by methods of Group I, classified in class 424, subclass 184.1.

IV. Claims 18 and 22-31, drawn to a method for producing a lymphocyte having tolerance to an allergen or an antigen comprising incubating an APC with a lymphocyte, classified in class 435, subclass 325.

Note: each claim will be examined only to the extent of the non-elected invention.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are unique methods. Groups I/IV, II and III differ with respect to their endpoints being drawn to a method for producing a lymphocyte or APC having tolerance to an allergen or an antigen, use of a composition capable of upregulating expression of an endogenous Notch or Notch ligand in an APC or lymphocyte , and a method of treating a patient suffering from a disease. Though the endpoints o Groups I and IV are the same, the groups differ with respect to their process steps since the method steps of Group I comprises incubating a lymphocyte or APC with a composition capable of upregulating expression of an endogenous Notch or Notch ligand and the allergen or antigen, and the method steps of Group IV comprises incubating an APC with a lymphocyte. Therefore, Groups I-IV are patentably distinct each from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention of a method which comprises:

A) notch or notch ligand
B) a composition capable of upregulating expression of endogenous notch or notch ligand,
C) "lymphocyte or antigen presenting cell"

Regardless of which group is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example applicant is required to elect a method comprising:

A) a **specific notch or notch ligand**, such as one recited in claim 8, and

B) a **specific composition** comprising a specific number and identity of ingredient(s) of said composition, such as one of the polypeptides recited in claims 6 or 7.
And
C) a **specific cell** in each case of the recitation of the phrase "lymphocyte or antigen presenting cell".

The species are distinct because each of said species has a distinct structure with distinct biochemical properties which are conferred by said distinct sructure.

Currently, claims 1-34 are generic in at least one respect.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux 2-10-03
Amy DeCloux, Ph.D.,
Patent Examiner,
Group 1640
February 10, 2003